K031685 Page 1 of 2

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JUL 1 2003

Smith+Nephew

SECTION V
510(k) Summary

Tag Rod BioRaptor™ Suture Anchor - Modification

Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810
508. 261.3699

B. Company Contact

Jason Bilobram
Senior Regulatory Specialist

C. Device Name

Trade Name:	Tag Rod BioRaptor™ 2.9 mm Suture Anchor
Common Name:	Suture Anchor
Classification Name:	Class II, Smooth or Threaded Metallic bone fixation fastener Product Code: JDR Suture, Nonabsorbable, Synthetic, Polyester Product Code: GAS

D. Predicate Devices

Acufex™ Bioabsorbable Tag Suture Anchors (K961555)

E. Description of Device

The Tag Rod BioRaptor 2.9 mm suture anchor is a push-in bioabsorable device utilized for the reattachment of soft tissue to bone.

F. Intended Use

The Tag Rod BioRaptor 2.9 mm suture anchor is intended for the reattachment of soft tissue to bone.

The indications for the Tag Rod BioRaptor 2.9 mm suture anchor are:

1. Bankart Lesion Repair
2. Rotator Cuff Repair
3. Capsular Stabilization
4. Anterior Shoulder Instability Repair
5. Repair of ligaments and tendons of the elbow, foot, and ankle including the treatment of:
    - Bunionectomy
    - Lateral ankle instability
    - Biceps tendon reattachment

G. Comparison of Technological Characteristics

Both the Tag Rod BioRaptor 2.9 mm suture anchor and the Tag Rod II 3.7 mm suture anchor are bioabsorbable suture anchors that are intended for the reattachment of soft tissue to bone.

Jason Bilobram

Senior Regulatory Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2003

Mr. Jason Bilobram
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
160 Dascomb Road
Andover, MA 01810

Re: K031685
Trade/Device Name: Tag Rod BioRaptor™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 27, 2003
Received: June 3, 2003

Dear Mr. Bilobram:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K031685

Device Name: Tag Rod BioRaptor™ 2.9 mm Suture Anchor

Intended Use: Reattachment of soft tissue to bone

Indications for Use :

1. Bankart Lesion Repair
2. Rotator Cuff Repair
3. Capsular Stabilization
4. Anterior Shoulder Instability Repair
5. Repair of ligaments and tendons of the elbow, foot, and ankle including the treatment of:
   - Bunionectomy
   - Lateral ankle instability
   - Biceps tendon reattachment

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-the-Counter No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031685